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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/526,325	02/28/2005	Roderick A. Capaldi	1505-67298-02	8934
24197 7590 11/16/2007 KLARQUIST SPARKMAN, LLP 121 SW SALMON STREET SUITE 1600 PORTLAND, OR 97204			EXAMINER VANDERVEGT, FRANCOIS P	
			ART UNIT 1644	PAPER NUMBER
			MAIL DATE 11/16/2007	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/526,325

Applicant(s)

CAPALDI ET AL.

Examiner

F. Pierre VanderVegt

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 August 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2,6-10,13,15,16,18-24,26,27,29-34,36,38 and 41-46 is/are pending in the application.
- 4a) Of the above claim(s) 27 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 34,36,38,41,42,44 and 46 is/are allowed.
- 6) ☒ Claim(s) 1,2,6-10,13,16,18,19,21,29,43 and 45 is/are rejected.
- 7) ☒ Claim(s) 15,20,22-24,26 and 30-33 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>20050228</u> . | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

This application is a Rule 371 continuation of PCT Serial Number PCT/US03/27306, which claims the benefit of the filing date of provisional U.S. Application 60/407,376.

Claims 3-5, 11, 12, 14, 17, 25, 28, 35, 37, 39, 40, 47 and 48 have been canceled.

Claims 1, 2, 6-10, 13, 15, 16, 18-24, 26, 27, 29-34, 36, 38, and 41-46 are currently pending.

Election/Restrictions

1. Applicant's election of Group I, claims 1, 2, 6-10, 13, 15, 16, 18-24, 26, 29-34, 36, 38, and 41-46 in the reply filed on August 23, 2007 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).
2. Claim 27 is withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on August 23, 2007.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claim 21 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter that was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Claim 21 recites "the electron acceptor dye molecule is selected from diaphorase, resazurin, and a combination thereof. The claim is not enabled because diaphorase is not an electron acceptor dye molecule. Diaphorase is a catalyst that transfers electrons to a dye. See column 2, lines 31-40 of U.S. Patent No. 6,380,380 to Kaufman (A on form PTO-892), for example. Accordingly, diaphorase would not be operative as claimed

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The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 8, 13, 19, 43 and 45 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 8 and 43 are ambiguous and unclear in reciting "releasing the immunocomplex complex" in part (i). There is no indication what it is to be released from.

Claim 13 recites the limitation "the immunocaptured" in parts (i) and (ii) of the claim. There is no antecedent basis for this limitation in base claim 1.

Claim 19 is ambiguous and unclear in reciting "transferring an electron from reduced NADH to an electron acceptor molecule to produce NADH" because the molecule remains reduced.

Claim 45 is ambiguous and unclear in reciting "high throughput screening" because this is not a "detecting" step. It is merely a general method and is not functionally equivalent to the "contacting" more specifically defined in part (i).

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 1, 2, 6-10, 13, 16, 18, 29 are rejected under 35 U.S.C. 102(b) as being anticipated by Suhr (J Immunol. [1990]144(7):2647-2652; U on form PTO-892, of record).

Suhr (J Immunol. [1990]144(7):2647-2652; U on form PTO-892) teaches monoclonal antibodies that bind to the E-2 domain of pyruvate dehydrogenase and distinguish it from protein X, another autoantigen in biliary cirrhosis (Abstract in particular). Suhr teaches the binding and detection of the immunocomplex on a microtiter plate [claims 9, 10] and the removal of non-complexed components of the sample [claim 7] (page 2648 in particular). Suhr further conducts an antibody inhibition assay determining the activity of the bound enzyme [claim 13], monitoring NADH production [claims 16, 18] (page 2648, column 2 in particular) and that the enzyme retains at least partial activity [claim 6]. Suhr

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further separates the immunocomplex by SDS-PAGE [claim 8] (figure 2 in particular). The prior art teaching anticipates the claimed invention.

Conclusion

6. Claims 15, 20, 22-24, 26 and 30-33 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.


7. Claims 34, 36, 38, 41, 42, 44 and 46 are allowed.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to F. Pierre VanderVegt whose telephone number is (571) 272-0852. The examiner can normally be reached on M-Th 6:30-4:00 and Alternate Fridays 6:30-3:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

F. Pierre VanderVegt, Ph.D. /PV/
Patent Examiner
November 13, 2007



DAVID A. SAUNDERS
PRIMARY EXAMINER